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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/453,726 12/02/99 READ

D 52951-USA-7A

EXAMINER

IM22/0718

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CHORBAJI, M

ART UNIT

PAPER NUMBER

1744

DATE MAILED:

07/18/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/453,726

Applicant(s)

READ, DAVID M

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 5-6, 9-11, 15-16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio (U.S.P.N. 6,063,631) in view of Lent et al (U.S.P.N. 4,756,758).

With respect to claims 1, 5-6, 9-11, 15-16, and 19-20, Ignacio teaches the following concepts: hydrogen peroxide indicator (abstract, lines 1-6) comprising a substrate (figure 1, 14) and an indicator composition (col.1, line 11 and figure 1, 12) disposed thereon (col.1, lines 11-12); the indicator composition comprises at least one colorant that changes color upon contact with hydrogen peroxide vapor (col.1, lines 15-20) and another colorant that does not change color upon contact with hydrogen

peroxide (col.2, lines 18-20); the substrate is a polyester film (col.1, line 31); method of monitoring a hydrogen peroxide sterilization process (col.1, lines 15-16); and wherein the binder is shellac (col.2, lines 41-43).

With respect to claims 1, 5-6, 9-11, 15-16, and 19-20, Ignacio does not explicitly teach the specific types of colorants used.

With respect to claims 1, 5, 10, and 15, Lent et al teaches the following concepts in the art of monitoring hydrogen peroxide sterilization process (abstract, lines 17-19 and col.1, lines 48-50): the use of ethyl violet as colorant (col.4, line 9). Furthermore; Lent et al teaches that one skilled in the art would be able to use other types of dyes which are available in the Color Index Guide. Thus, one skilled in the art would have been motivated to combine the teachings of Ignacio with Lent et al in order to design a composition that exhibit sufficient adhesion to the substrate to withstand the moisture and high temperature conditions of sterilization and which at the same time undergo a visible permanent color change (Lent et al, col.1, lines 42-47).

4. Claims 2, 4, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio (U.S.P.N. 6,063,631) in view of Davies et al (U.S.P.N. 4,863,627).

The teachings of Ignacio have previously been set forth with regard to claims 1, 5-6, 9-11, 15-16, and 19-20.

Ignacio does not teach the following concepts: the use of Brilliant green as a colorant.

With respect to claims 2, 4, 12, and 14, Davies et al teaches the following concepts in the art of sterilizing and disinfecting using hydrogen peroxide and a colorant such as Brilliant green (example 7) that changes color upon exposure to hydrogen peroxide (col.1, lines 5-13 and col.4, lines 17-18). Thus, one skilled in the art would have been motivated to combine the teachings of Ignacio with Davies et al in order to insure that the disinfecting agent has been inactivated by the inactivating agent (Davies et al, col.3, lines 15-18).

5. Claims 3, 7-8, 13, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ignacio (U.S.P.N. 6,063,631) in view of Patel et al (U.S.P.N. 5,420,000) and further in view of Barrett (U.S.P.N. 5,955,025).

The teachings of Ignacio have previously been set forth with regard to claims 1, 5-6, 9-11, 15-16, and 19-20.

Ignacio does not teach the following concepts: the use of Alkali blue 6B; and the use of Quinacridone red 19.

With respect to claims 3, 8, 13, and 18, Patel et al teaches the following concepts: In the art of sterilization (col.32, lines 43-45) wherein Alkali blue 6B is known to be used (col.25, lines 27-36).

Patel et al does not teach the use of Quinacridone red 19.

With respect to claims 7, 8, 17, and 18, Barrett teaches in the art of sterilization the use of Quinacridone red 19 (col.4, table). Thus, one skilled in the art would have been motivated to combine the teachings of Ignacio, Patel et al, and Barrett in order to

design a suitable indicator imminently useful with the chemical vapor phase sterilization processes and also to provide a process for indicating when an article has been subjected to a sterilization process (Barrett, col.2, lines 6-8 and 18-20).

Conclusion

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Malchesky et al (U.S.P.N. 5,518,927), Fujisawa (U.S.P.N. 5,087,659), and Muzyczko et al (U.S.P.N. 4,046,577) teach other similar concepts in the art of using indicators in sterilization processes.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.
8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

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9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744
July 6, 2001

Robert J. Warden, Sr.
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